K132333
JUN 25 2014

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Section 5 – Traditional 510(k) Notification:- 510(k) Summary

This Traditional 510(k) notification is to provide substantial equivalence for Medtrade Products Bondiloxs Topical Hemostatic Dressing, which is substantially equivalent to currently marketed hemostatic dressings intended for temporary external treatment for controlling minor and moderate to severe bleeding.

1. Submitted by:

Medtrade Product Ltd
Electra House, Crewe Business Park
Crewe, Cheshire
CW1 6GL
United Kingdom

Establishment Registration Number: 9614493

Contact Person:-
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Quality & Regulatory Director
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2. Date Summary prepared:

24thth June 2014

3. Device Information:-

Proprietary Name:	Bondiloxs Topical Hemostatic Dressing
Common Name:	Bondiloxs Topical Hemostatic Dressing
Trade Names:	Not yet defined
Product Code:	FRO
Classification Name:	Dressing, Wound, Drug
Classification:	Unclassified

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4. **Predicate Devices:**
CELOX Gauze PRO 510(k) # K113560, manufactured by Medtrade Products Ltd.

5. **Device Description:-**
Bondiloxs Topical Hemostatic Dressing is a sterile non-woven dressing comprising of chitosan fibres which aids the gelling and absorbency potential of the dressing.

Bondiloxs Topical Hemostatic Dressing achieves the principle intended action of hemostasis by the providing a physical barrier to stop bleeding. By applying the Bondiloxs Topical Hemostatic Dressing directly onto a wound and together with firm pressure the gel-like plug on dressing's surface creates a physical barrier which controls blood flow through the dressing to stop bleeding.

The dressing promotes localized clotting formation to help stop bleeding.

The Bondiloxs Topical Hemostatic Dressing is packed in a foil/foil pouch. The pouch provide an integral barrier that maintains dressing sterility post irradiation yet allows easy opening and aseptic dressing removal by the end user.

The Bondiloxs Topical Hemostatic Dressing is available in various sizes ranging up to a maximum of 15cm x 15cm and is available in a flat dressing or z-folded for fast and intuitive application.

6. **Indication for Use:-**
Under the supervision of a healthcare professional Bondiloxs Topical Hemostatic Dressing is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures and for temporary external treatment for controlling moderate to severe bleeding.

7. **Substantial Equivalence:-**
The Bondiloxs Topical Hemostatic Dressings has identical indications for use to the legally marketed Medtrade Products CELOX Gauze Pro (510(k) # K113560)

Which is a chitosan based dressing.

The following tabulations which summarises the description, Indications for use, and general information, and the substantial equivalence information provides a succinct and direct comparison of equivalence between Bondiloxs Topical Hemostatic Dressings and the approved predicate device listed above.

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Summary of Comparison of Bondiloxs Topical Hemostatic Dressing and the Predicate Device

	Bondiloxs Topical Hemostatic Dressings	CELOX Gauze PRO (510(k) # K113560)
Description	Bondiloxs Topical Hemostatic Dressing is sterile non-woven dressing comprising of chitosan fibres and lactic acid which aids the gelling and absorbency potential of the dressing.	The device consists of a chitosan Haemostatic granules adhered onto a base fabric (non woven gauze) using a hot melt adhesive.
Physical Composition	Chitosan fibres and lactic acid non-woven, soft, non fibrous absorbent dressing	Chitosan Granules on Sheet
Indications for Use /RX only)	Under the supervision of a healthcare professional Bondiloxs Topical Hemostatic Dressing is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures and for temporary external treatment for controlling moderate to severe bleeding.	Under the supervision of a healthcare professional CELOX Gauze PRO for moderate to severe external bleeding wounds (Rx) is intended for temporary external treatment for controlling moderate to severe bleeding.

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	Bondiloxs Topical Hemostatic Dressings	CELOX Gauze PRO (510(k) # K113560)
Indications for Use /RX only) (Continue)		Under the supervision of a healthcare professional CELOX Gauze PRO for minor external bleeding from wounds and procedures (Rx) is intended for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

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	Bondiloxs Topical Hemostatic Dressings	CELOX Gauze PRO (510(k) # K113560)
Product Code	FRO	FRO
For single use only	Yes	Yes
Method of sterilisation	Gamma Irradiation in accordance with ISO 11137	Gamma Irradiation in accordance with ISO 11137
Sterility assurance level	1x10-6	1x10-6
Biocompatibility testing completed in accordance with ISO 10993	Yes	Yes
Mode of Action	Bondiloxs Topical Hemostatic Dressing achieves the principle intended action of hemostasis by the providing a physical barrier to stop bleeding	CELOX Gauze PRO achieves the principle intended action of hemostasis by the providing a physical barrier to stop bleeding.

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8. Manufacturing:-

Bondiloxs Topical Hemostatic Dressing is manufactured according to the product specifications and under good manufacturing practices (GMP). A risk analysis has been performed in accordance with BS EN ISO 14971 to identify possible failure mode during manufacturing and design. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

Bondiloxs Topical Hemostatic Dressings meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

Bondiloxs Topical Hemostatic Dressings are terminally sterilised by gamma irradiation to a sterility assurance level (SAL) of 10^{-6}.

9. Non-Clinical Performance Data:-

Performance data for the Bondiloxs Topical Hemostatic Dressing has been established using *in-vivo* testing (Hemostatic properties) and bench testing in accordance to relevant standards where applicable (including absorbency, tensile strength, gelling properties, pack integrity (dye penetration and burst test) and sterility testing.

The *in-vivo* studies were designed and conducted to establish the hemostatic efficacy of the Bondiloxs Topical Hemostatic Dressing in different injury types, including; Epigastric artery wound model with both heparinised and non-heparinised conditions, Liver cruciate model (represents mild to moderate bleeding), liver dissection model (to assess hemostatic efficacy for moderate bleeding), Epigastric sever model (to assess hemostatic efficacy for mild topical bleeding) and Saphenous femoral 2.7mm punch (to assess hemostatic efficacy for moderate to major bleeding).

The Bondiloxs Topical Hemostatic Dressing is restricted to external, topical (dermal) use and the various animal models were used to assess the ability of the device to control different severities of bleeding.

Shelf Life has been determined using stability studies at ambient conditions (real time aging 25°C/60% RH) and in an environment in which the temperature and relative humidity have been controlled at 40°C/75% RH.

The biocompatibility of Bondiloxs Topical Hemostatic Dressing has been demonstrated through assessment according to BS EN ISO 10993-1 (Biological Evaluation of Medical Devices) and appropriate testing these include cytotoxicity, sensitization and irritation. The biocompatibility testing for the Bondiloxs Topical Hemostatic Dressing has demonstrated that the device is safe for the indications of use.

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Sterilisation validation has been performed in compliance with harmonised standards (ISO 11137-1: 2006 – Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices).

The biocompatibility and performance testing including the *in vivo* testing for the Bondiloxs Topical Hemostatic Dressing has demonstrated that the device is safe and effective for the indications of use.

10. Clinical Performance Data:

Based upon the substantial equivalence determination for the predicate device (CELOX Gauze Pro (510(k) # K113560 no clinical data is required for evaluation of the Bondiloxs Topical Hemostatic Dressing.

11. Conclusion

The indication for use and performance testing for the Bondiloxs Topical Hemostatic Dressing is substantially equivalent to the predicate device; CELOX Gauze Pro (510(k) # K113560) manufactured by Medtrade Products Ltd.

The Bondiloxs Topical Hemostatic Dressing is indicated for topical application as for the control of temporary external bleeding associated with minor to severely bleeding wounds.

The biocompatibility and performance testing for the Bondiloxs Topical Hemostatic Dressing has demonstrated that the device is as safe and effective as the predicate devices and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2014

Medtrade Product Ltd
Mr. Jonathan Ranfield
Quality & Regulatory Director
Electra House, Crewe Business Park
Crewe, Cheshire
CW1 6GL
United Kingdom

Re: K132333
Trade/Device Name: Bondiloxs Topical Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 19, 2014
Received: March 24, 2014

Dear Mr. Ranfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K132333

Device Name: **Bondiloxs Topical Hemostatic Dressing**

Indications for Use:

Under the supervision of a healthcare professional **Bondiloxs Topical Hemostatic Dressing** is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures and for temporary external treatment for controlling moderate to severe bleeding.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S